Surgical Pathology & FNA of the Breast and the Law
David L. Page, Vanderbilt

Any aspect of the process of specimen acceptance, processing and transport of a diagnosis is ‘liable’ to go awry

ACCOUNTABILITY, RESPONSIBILITY
& OVERCONCERN FOR LEGAL CONSEQUENCES

© 2005 College of American Pathologists. Materials are used with the permission of the faculty.
Incompetence and Negligence

- Gross negligence, simple negligence
- “Malpractice”- unique standard in each case with jury following the instructions of the judge based on the testimony of expert witnesses.
- G.G. Davis and M.A. Scott
Pillars of Malpractice

- Duty = Obligation to treat for a pathologist is provision of guidance to treating physician(s)
- Dereliction - standard of care
- Damage - more than ‘worse’
- Cause - substantial factor
Pathologist frontage in breast disease is wrongful diagnosis

- Usually **overdiagnosis** of malignancy
- Considering the magnitude of treatment consequences, old practice of ‘erring on side of malignancy to benefit patient’ is long irrelevant.
- **Underdiagnosis** of malignancy, also often includes lack of clinical......
Diagnostic Statement

- Clarity and Certainty
  - if certain, so state
  - if uncertain, relay that with certainty

- 1st degree Dx=“acute appendicitis”

- 2nd degree Dx= c/w...

- 3rd degree Dx=inflammation, see comment
Diagnostic Statement

- **Clarity and Certainty**
  - if certain, so state
  - if uncertain, relay that with certainty

- **1st degree** Dx = DCIS, INT. GRADE

- **2nd degree** Dx = c/w...DCIS, NEED..

- **3rd degree** Dx = ATYPICAL CELLS, see comment
“If you as a pathologist discover that you have made an error of such magnitude, then you need to immediately make it your business to start getting the truth out”

This will involve contact with the clinician and often the patient.

Delay while you seek your own legal counsel may be inadvisable. And any actions taken will be part of the overall record.
Real Cases

- “Invasive ductal carcinoma”
- Followed by mastx., 5 courses of ChemRx and first review of original exc. biopsy at time of liver scan
- Dx= sclerosed, adenotic papilloma of 1.1cm, completely excised at first.
- Surgeon and Med. Oncologist not sued because diagnosis is clear, even though other information might have been sought.
Special Cases - Breast FNA

- You perform the FNA and find out that a pneumothorax has ensued.
- You ‘over’ or underdiagnose the FNA.
- What does ‘malignant cells present’ really mean?
- NCI Consensus Conference in 1996 supports a likelihood approach to reporting. Similar to Papanicolaou
Reporting of Breast FNA

- The initial version of this paper was published in *Diagnostic Cytopathology*, Vol. 16, No. 4, 1997
Real Case(s) FNA, Breast

- Location, location, location
- ‘Lump’, Cyst, solid, old, young
- Clinical (Mis) information
- “the cells looked so malignant”
- Fibroadenoma, apocrine and regenerative/inflammatory change in cyst and other
Real Cases, FNA Breast

- Path requisition form = breast lump
- Clinical notes - cyst fluid aspirated
- Dx: few malignant cells present c/w carcinoma
- Outcome: bilateral mastectomy in young woman with uncertain positive family history and fear.
Lowell Rogers, 1976

- "No matter how carefully worded and constructed the diagnosis may be, there is a clinician somewhere anxious to misinterpret it"

- This emphasizes the importance of the insight of the receptor(s) of our diagnoses, and the luxury of knowing their strengths and weaknesses.
CAP lab inspection long involved in liability and clear responsibility of reporting

- Intraoperative diagnostic reports must be in writing and signed by the pathologist who made the diagnosis
**Liability**

- Wrongful diagnosis - leading to harm
- This is overdiagnosis of cancer and implicated the clinician in ‘over treatment, but.....usually the pathologist goes to see the judge and jury alone
- Even, if the clinician has been a party to encouraging a Dx. Of Cancer
Special Responsibility of Consultants

- This should take into account prior diagnostic opinions - and be clear
- This may involve specific discussions of prior opinions or not
Hypersecretory changes in a single Lobular Unit
Clustered atypical apocrine cytology changes
Reactive nuclear changes atop infarcted Papilloma
Most common Diagnostic Mistakes in Breast Pathology

- Few Atypical cells by cytology called 'cancer' without supporting features of pattern and extent (FNA or Biopsy)
- Unusual and unfamiliar distorted stroma and glands called infiltrating CA = Sclerosing adenosis less common than sclerosed/adenotic papillomas
Real Case

- Diagnosis of DCIS leads to Mastectomy and later review at major Cancer Center
- 2nd Diagnosis = B9
- Suit filed, and outcome is likely at pretrial settlement
- Because DCIS is intermediate grade, Apocrine type, a diagnosis clearly controversial from available literature
“False Negative” FNA-Breast

- Not usually a serious breach because of the pervasive understanding of the concept of the “Triple Test”

Answer: solitary group of “odd” cells in B9 bx. With Proliferative…
CONCLUSION

Cannot practice diagnostic Pathology of Breast Disease without understanding what is beyond the cells encased in glass.